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## P061

# The UK Clinical Trials Accelerator Platform - a national cystic fibrosis clinical trials network increasing access to clinical trials for the UK cystic fibrosis community

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The Clinical Trials Accelerator Platform (CTAP) is a national cystic fibrosis (CF) clinical trials network, funded by the Cystic Fibrosis Foundation (CFF). The UK Cystic Fibrosis Trust set up and manages the programme, working in synchrony with the European Cystic Fibrosis Society's Clinical Trials Network (ECFS-CTN) and collaborating with the CF clinical community to provide sponsors with parallel access to trial participants.

Through the following workstreams, CTAP supports the CF community in accessing a breadth of clinical trials, whilst supporting sponsors with trial delivery:

- Network of centres: 27 CF centres form the CTAP network, providing coverage of 89% of the UK CF population. 19/27 centres are funded with a CTAP Coordinator to oversee local trial delivery
- 2. **CF Ambassadors:** CF Ambassadors (pwcf and CF parents) represent the therapeutic needs of the CF community and collaborate with sponsors to make recommendations on trial design and outcomes
- Sponsor Engagement: CTAP supports commercial and academic sponsors by offering a centralised feasibility service to support site selection and facilitating engagement with CF Ambassadors
- CF Clinical Trials Hub: Hosted on the Cystic Fibrosis Trusts website, the hub has a suite of information about clinical trials, including the CF Trials Tracker database

Since launch in autumn 2017, CTAP metrics show  $\sim$ 9% of the UK CF population have been screened for a trial within the CTAP network,  $\sim$ 7% of whom went on to enroll. Awareness of clinical trials in people with CF increased from 60% in 2017 to 71% in 2020.

Through the infrastructure created, guidance from CFF and alignment with the ECFS-CTN, CTAP has established a clear pathway for sponsors to invest CF trials in the UK. This, alongside the information hub created for the CF community, has enabled CTAP to maximise a unique opportunity to lead a positive culture change in the UK, becoming a significant contributor to the global effort for CF drug development.

# P062

# Impact of the SARS-CoV-2 pandemic on clinical trials in the ECFS-CTN during $2020\,$

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Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has disrupted clinical trials. The European Cystic Fibrosis Society-Clinical Trials Network (ECFS-CTN) tracked disruption to CF trials via regular surveys to adult and paediatric clinics of member sites throughout 2020. We published preliminary results to May 2020 (doi: 10.1183/ 13993003.02114-2020). Here we report updated data to the end of 2020. Ongoing trials were heavily impacted up to May. Trial participant visits, new enrollment and monitoring visits were widely banned, with frequent home delivery of study drug (Table 1). From June to December, trial visits, new enrollment and onsite monitoring were mostly allowed, and home delivery of study drug dropped accordingly. The set-up of new trials was heavily impacted in March but recovered substantially from June on. Some sites had reduced staff available to work on CF trials. Table 1 presents how remote visits and measures were used by sites from June to December. Much of the early trial disruption resolved by end 2020: however. challenges remain to protect the progress of clinical research in CF during the pandemic.

#### P063

## Community involvement in shaping cystic fibrosis clinical trials

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The value and benefit of involving people with 'lived experience' of the condition a clinical trial aims to address has been well documented. It is widely acknowledged that the inclusion of 'Patient & Public Involvement' (PPI) at all stages of the trials process leads to better design with improved recruitment and retention rates. PPI is also regarded as a highly important component of the UK regulatory process, with sponsors strongly encouraged to include PPI at the earliest possible stage of planning.

Table 1. (abstract: P062)

| Date of data collection<br>Number of evaluable responding clinics |  | 24-Mar | 27-Mar | 10-Apr | 04-May | 17-Jun | 29-Jul | 21-Oct | 02-Dec |
|---|--|--------|--------|--------|--------|--------|--------|--------|--------|
|   |  | 59     | 55     | 61     | 63     | 45     | 48     | 54     | 62     |
| Ongoing trials, the % of clinics allowing:                        | Patients to attend onsite<br>trial visits            | 71%    | 60%    | 57%    | 75%    | 84%    | 94%    | 98%    | 98%    |
| Ū   | New enrollment into<br>ongoing trials                | 22%    | 15%    | NA     | NA     | 77%    | 85%    | 85%    | 90%    |
|   | Onsite clinical research associate monitoring visits | 16%    | 11%    | NA     | NA     | 69%    | 83%    | 80%    | 76%    |
|   | Study drug shipped to patients                       | 55%    | 66%    | 67%    | 65%    | 33%    | 34%    | 28%    | 34%    |
| For new trials, the % of clinics allowing:                        | Trial set-up activities to continue                  | 57%    | 60%    | 52%    | 71%    | 84%    | 92%    | 90%    | 90%    |
|   | Site initiation visits                               | 5%     | 14%    | NA     | NA     | 78%    | 83%    | 85%    | 74%    |
|   | Initiation of CFTR<br>modulator extension<br>studies | 91%    | 78%    | NA     | NA     | 91%    | 94%    | 92%    | 94%    |
| Staff availability reduced?                                       |  | NA     | NA     | 59%    | 53%    | 24%    | 19%    | 24%    | 26%    |
| Remote measures (% of   | Telephone visits                                     | NA     | NA     | NA     | NA     | 71%    | 77%    | 74%    | 74%    |
| clinics that used   | Video visits   | NA     | NA     | NA     | NA     | 22%    | 29%    | 33%    | 24%    |
| measures)   | Remote/home spirometry                               | NA     | NA     | NA     | NA     | 27%    | 23%    | 28%    | 21%    |
|   | Home health services for<br>blood draws              | NA     | NA     | NA     | NA     | 16%    | 23%    | 15%    | 18%    |
|   | Electronic consent                                   | NA     | NA     | NA     | NA     | 27%    | 29%    | 30%    | 21%    |